UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

BAYER HEALTHCARE LLC;

Plaintiff,

v. **Case No. 08-C-953**

NORBROOK LABORATORIES, LTD., and NORBROOK, INC. USA;

Defendants.

DECISION AND ORDER

This Decision and Order addresses Plaintiff Bayer Healthcare LLC's ("Bayer") motion to compel production pursuant to its April 11, 2011, discovery requests to Defendants Norbrook Laboratories, Ltd. and Norbrook, Inc. U.S.A.'s (collectively referred to as "Norbrook"), and Bayer's contention regarding the July 8, 2011, declaration of Lillian Cromie, Ph.D, ("Cromie"), Norbrook Laboratories, Ltd.'s Director of Licensing and its former Head of Research and Development, that Norbrook filed in support of its opposition to the motion to compel. The discovery dispute relates to the scope of permissible discovery with respect to Norbrook's contention that claims 4 and 5 of United States Patent Number 5,756,506 (the "'506 patent"), which pertains to the treatment of animals with fluoroquinolones in a single

high dose to replace multiple lower doses are invalid, for lack of enablement as required by 35 U.S.C. § 112. *See ALZA Corp. v. Andrx Pharms., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010).

ISSUE RELATING TO CROMIE DECLARATION

Subsequent to the completion of the briefing of Bayer's motion to compel, with the Court's permission, Bayer filed a letter dated October 5, 2011, and attachments that it stated supplemented and corrected its motion. On October 12, 2011, Norbrook filed a response to that letter, contesting Bayer's contentions. The Court addresses the issue raised by the October 5, 2011, letter since it could impact resolution of the motion to compel.

Bayer asserts that Cromie's subsequent deposition testimony reveals flaws in her prior declaration.

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Cromie indicated that "to *my knowledge*, only of [sic] a few of the fluoroquinolones referenced in the

patent-in-suit in this case were commercially available around the 1995 timeframe when the patent was filed. . . . *I do not specifically remember* any fluoroquinolone injectable products available on the market for treatment of bovine respiratory disease in the 1995 timeframe." (*Id*. at ¶ 8.) The foregoing statements in paragraph eight of Cromie's declaration were based on her knowledge and recollection.

At Cromie's August 25, 2011, deposition, she was shown two documents that Bayer obtained by means of an internet search which included a link to a CDC ("Center for Disease Control") article produced by that search. (Bayer's October 5, 2011, letter, Ex. B 290-92, referring to Exs. C & D to such letter.) The CDC article indicates that by the 1995 time frame, three quinolones had been licensed: marbofloxacin licensed in 1993 in cattle in France; danofloxacin licensed in cattle and pigs in 1993 in Japan; orbifloxacin, licensed in 1993, in cattle and pigs; and "United Kingdom," marbofloxacin, licensed in 1995 for cattle. (Bayer's October 5, 2011, letter, Ex. B 290-92, Ex. D.) While Bayer contends that the search results revealed flaws and inconsistencies in Cromie's declaration, the additional information disclosed by those searches did not change what Cromie knew or recalled at the time of her declaration.

Additionally, there is no indication that "licensing" means "commercially available." The CDC article states "licensing for use does not necessarily mean that the drug is actually used, so even these data have to be considered with caution." (Bayer's October 5, 2011, Letter, Ex. D 2 of 7.) The CDC article also discusses the use of the drugs for

gastrointestinal diseases; not respiratory diseases. The supplemental information provided by Bayer will be considered by the Court, but it does not seriously undermine the proposition advanced by Norbrook that the formulation work on non-fluroquinolone drugs on which Bayer seeks discovery does not bear a logical relationship to the work on fluroquinolone drugs because there is considerable difference between (a) the amount and nature of formulation and testing work necessary to produce a drug with an active ingredient that is already commercially available to treat a particular disease and (b) the amount and nature of such work that would be required to develop a drug with an active ingredient that has not been commercialized and/or that is to be put to a new use.

BAYER'S MOTION TO COMPEL

Having addressed the preliminary issue regarding Cromie's declaration, the Court considers Bayer's motion to compel Norbrook's production of discovery sought by: Requests Numbers 56 through 57, 62, and 65 through 66 of Bayer's April 11, 2011, Request for Production of Documents and Things (Numbers 47-73); Interrogatories Numbers 24, and 26 through 29 of Bayer's April 11, 2011, Set of Interrogatories (Numbers 23-35); Rule 30(b)(6) Deposition Topics Numbers 1 through 5 of Bayer's April 11, 2011, Notice of Deposition Topics (Numbers 1-25). Bayer indicates that it has limited its April 11, 2011, discovery requests to the following injectable products: Amoxicillin injectable referenced in Norbrook's Suitability Petition, Number 95P-0036/CP1; Carprieve 50 mg/ml; Dihydrostreptomycin Sulfate (NADA 065-013); Enovex 1.0% w/v; Norocarp 50 mg/ml;

Norocillin (NADA 065-010); Penicillin G Procaine Aqueous / Sterile Penicillin G Benzathine (NADA 065-500); and its oxytetracycline formulations, including any information about formulations referenced in Norbrook's Suitability Petition, Number 92P-0490/CP1. Bayer also states "where applicable its requests are further limited to information sufficient to show the requested information." (Bayer Mot. Compel 2.) Norbrook has only responded to Bayer's discovery requests as to fluoroquinolones.

Bayer's motion to compel arises as a result of the disparity between Norbrook's response to the April 11, 2011, discovery requests and those drugs for which Bayer has requested discovery. Bayer contends that the principles of the formulation of fluoroquinolones extend to formulations of other types of drugs and, therefore, it should be allowed to obtain discovery regarding non-fluoroquinolones. Norbrook asserts that discovery regarding non-fluoroquinolones is not relevant and, even if it were relevant, any relevance would be far outweighed by the burden associated with Norbrook's production of such documents, information, and testimony.

The present discovery issues are based on Norbrook's contention that claims 4 and 5 of the '506 patent, the only claims at issue in this action, are invalid because a person of ordinary skill could not have prepared **REDACTED** using the disclosures of the '506 patent. The "[f]ield of the [i]nvention" is described as "The . . . treatment of animals with fluoro[]quinolones. More specifically, the present invention relates

to "the use of fluoroquinolones in a single high dose to replace multiple lower doses." ('506 patent, 1:10-12.)

Claims 4 and 5 read as follows (with claim 1 language incorporated in brackets):

> 4. [A process for treating a bacterial infection], wherein the bacterial infection is bovine respiratory disease, [in an animal in need thereof comprising administering to said animal a pharmaceutically effective composition comprising a fluoroquinolone, an ester, or a salt thereof in one high dose, single treatment.]
>
> 5. The process of claim 4 wherein the bovine respiratory disease is caused by Pasteurella, haemolytica or Pasteurella multocida.

(*Id*. at 4:10-14 & 24-29 (emphasis added).) Simply put the dispute between the parties is the breadth of the discovery that is relevant to Norbrook's enablement contentions.

Relevant Law

Rule 26(b) of the Federal Rules of Civil Procedure provides that "[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense – including the existence, description, nature, custody, condition, and location of any documents or other tangible things and the identity and location of persons who know of any discoverable matter." It also explains that "[r]elevant information *need not be admissible at the trial* if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." Fed. R. Civ. P. 26(b) (*emphasis added*.) Nonetheless, "[a]ll discovery is subject to the limitations imposed by Rule 26(b)(2)(C)." *Id*.

The limitations imposed by Rule 26(b)(2)(C) include the requirement that the Court "must" limit the frequency or extent of discovery if it determines that "the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive." *See* Fed. R. Civ. P. 26(b)(2)(C)(i). The Court must also impose such limitations if it determines that "the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues." *See* Fed. R. Civ. P. 26(b)(2)(C)(iii).

District courts have broad discretion in determining motions to compel. *See Peals v. Terre Haute Police Dep't*, 535 F.3d 621, 629 (7th Cir. 2008). In responding to a motion to compel discovery, the party that objects to the discovery request has the burden of demonstrating, with specificity, why the information sought is not discoverable. *Graham v. Casey's Gen. Stores*, 206 F.R.D. 251, 254 (S.D. Ind. 2002).

Since the discovery dispute relates to Norbrook's enablement contentions, a brief summary of the relevant legal principles is helpful. "To be enabling, the specification must teach those skilled in the art to make and use the *full scope* of the claimed invention without undue experimentation." *Genentech, Inc. v. Novo Nordisk*, 108 F.3d 1361, 1365 (Fed. Cir. 1997) (emphasis added). If the specification requires one of ordinary skill in the art to perform "*undue* experimentation" to practice the invention as broadly as it is claimed, the

patent is invalid for lack of enablement. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (emphasis added). However, "[e]nablement is not precluded by the necessity for some experimentation . . . ," and "[a] patent need not disclose what is well known in the art." *Id.* at 737, 735. Factors to consider in determining whether a disclosure requires undue experimentation include "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *Id.*

Analysis

In asserting that discovery should include drugs other than fluoroquinolones, Bayer relies on parts of the report of Norbrook's expert, Stephen R. Bryn, Ph.D. ("Bryn").[1] Bayer relies upon Bryn's statement at page 18 of his 21 page report that "[*t]he trial and error process* required to determine a 'pharmaceutically effective composition' demonstrated by Bayer *is typical of pharmaceutical companies.* Treating diseases in animals requires considerable effort by pharmaceutical companies to ensure that a non-toxic, effective formulation is developed." (Bayer's Mem. Support Mot. Compel 5 (quoting Simpson Decl. filed June 17, 2011, Ex. A (Bryn Report), ¶ 53).) Bayer further notes that, in his report Bryn relies on examples and principles from other drug classes than fluoroquinolones. (Id. (citing

[1]Bryn was the Head of the Department of Industrial and Physical Pharmacy at Purdue University from 1994 to 2009, and is currently the Charles B. Jordan Professor of Medicinal Chemistry at Purdue, a position he was appointed to in 1992.

Simpson Decl. filed June 17, 2011, Ex. A 10-11, 19).) From this, Bayer infers that it is entitled to discovery regarding Norbrook's other formulation research which Bayer believes will discredit Norbrook's contentions regarding the difficulty of preparing fluoroquinolone formulations.

Bayer also relies on the three page declaration of one of its experts, Anthony Palmieri III, Ph.D. ("Palmieri").[2] (*Id*. at 5-6 (citing Simpson Decl. filed June 17, 2011, Ex. E 2-3).) Palmieri states that while Byrn "directs his comments in some (but not all) portions of his report to fluoroquinolones, the scientific issues that he addresses apply more generally to the formulation of drug products in other classes as well. Experience and information regarding the formulation of drugs in other classes other than fluoroquinolones would certainly be relevant to an effort to refute the statements by . . . Bryn and his conclusions." (Simpson Decl. filed June 17, 2011, Ex. E ¶ 7.)

Bryn's report contains highly detailed explanations regarding why the patent specification does not provide sufficient information for enablement.

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[2]Palmieri is presently on the faculty at the University of Florida College of Pharmacy in the Department of Pharmaceutics.

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The Court concludes that, in asserting that Bryn's report provides a basis for the relevance of Norbrook's work on non-fluoroquinolones, Bayer has selectively read his report. Moreover, when read in full, Bryn's report establishes that the relevant chemical class of compounds with respect to enablement are fluoroquinolones. Discovery regarding the formulations of other chemical groups that are used as injectable drugs is not likely to lead to the discovery of admissible evidence on the enablement issue in this action. (*See also*, Cromie Decl. ¶¶ 6-10.) Norbrook has met its burden of establishing that discovery regarding the formulation of drugs in other classes other than fluoroquinolones is not likely to lead to the discovery of admissible evidence regarding enablement.[3] Palmieri's statements to the contrary are conclusory and without factual support in his declaration.

The three cases that Bayer relies upon in its reply brief to argue that the discovery sought is highly relevant to this case are not helpful. (*See* Bayer Reply Mem. Support Mot. Compel 9-10 (citing cases).) *Compagnie Noga d'Importation et d'Exportation S.A. v. Russian Fed'n*, No. 00 Civ. 0632 (WHP), 2008 WL 3833257, at *6 (S.D.N.Y. Aug.

[3]Notably, several district courts have determined that discovery must be limited by what is claimed in the patent. *See Wyeth v. Abbott Labs.*, No. 08-230 (JAP), 2011 WL 2429318, at *7 (D.N.J. June 13, 2011) (limiting scope of third-party subpoena to the specific use claimed in the patent at issue); *Pfizer Inc. v. Teva Pharms. USA, Inc.*, No. 08-1331 (DMC), 2009 WL 1587893, *2 (D.N.J. June 4, 2009) (where the patent-in-suit claimed only oral formulations, the inventors' efforts to develop nonoral formulations were irrelevant and any claim of relevance was purely speculative); *Monsanto Co. v. Aventis Cropscience, N.V.*, No. 4:00CV1915 ERW, slip op. at 11-13 (E.D. Mo. July 18, 2002) (Dkt. No. 150) (where the patent-in-suit involved "truncated" crop gene resistant to insects, the plaintiff's discovery demands for the defendants' work on "untruncated" crop gene were overbroad).

15, 2008), cited for the statement that the "[Plaintiff's] own documents undermine its expert's interpretation and support Defendant's expert's interpretation," involved the weighing of expert reports and does not relate to the scope of permissible discovery. *Cooley v. Lincoln Elec. Co.*, 776 F. Supp. 2d 511, 2011 WL 841535, at *17 (N.D. Ohio Mar. 7, 2011), involves a discussion of the weighing of expert testimony regarding whether there is a reasonable disagreement among experts that manganese in welding fumes can cause manganese poisoning. *Cooley* does not discuss the scope of discovery or relevance.

Bitler Inv. Venture II, LLC v. Marathon Ashland Petrol. LLC, No. 1:04-CV-477, 2007 WL 465444, at *7 (N.D. Ind. Feb. 7, 2007), addresses the scope of discovery regarding a damage expert's opinions and concluded after an *in camera* inspection that emails from a plaintiff to the expert were relevant to expert's opinion because they revealed that plaintiff's potential influence on the expert, thereby impacting the credibility of that expert's report. *Bitler* does not support Bayer's contention of relevance.

In addition, even if this Court had concluded that the information is relevant, Norbrook has demonstrated that the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues.

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Norbrook has demonstrated with specificity the excessive burden that the discovery will place upon Norbrook. Bayer indicates Norbrook overstates what Bayer is requesting, and that while Bayer wants documents relating to formulation development work, it has "consistently indicated its willingness to accept summary documents," (Bayer Reply Mem. Support Mot. Compel 13.) However, there is no indication that Norbrook has summary documents regarding its formulation development work. Thus, Bayer has failed to rebut Norbrook's showing that the requested discovery would create an undue burden. Because the burden that the discovery would impose upon Norbrook outweighs its relevance, Bayer's motion to compel production pursuant to its April 11, 2011, discovery requests to Norbrook is also denied on this basis.

Because many of the documents relating to and discussed in this Decision and Order relate to confidential information and are sealed, this Court finds good cause to seal this

Decision and Order. *See Cnty. Materials Corp. v. Allan Block Corp.*, 502 F.3d 730, 740 (7th Cir. 2007). The sealing order will expressly provide that any party and any interested member of the public may challenge the sealing of those papers. *See id.* A redacted version of this Decision and Order will be filed in the public record.

NOW, THEREFORE, BASED ON THE FOREGOING, IT IS HEREBY ORDERED THAT:

Bayer's motion to compel production pursuant to Bayer's April 11, 2011, discovery requests (Docket No. 201) is **DENIED**.

The Clerk of Court is **DIRECTED TO SEAL** this Decision and Order.

Any party and any interested member of the public **MAY CHALLENGE** the sealing of this Decision and Order.

The Clerk of Court is also **DIRECTED TO FILE A REDACTED VERSION** of this Decision and Order.

Dated at Milwaukee, Wisconsin, this 6th day of December, 2011.

BY THE COURT:

HON. RUDOLPH T. RANDA
U.S. District Judge